6.5.1. Approvals for hygienic applications

Materials & Material Surfaces

Materials and their surfaces play a central role in the hygienic design of machines and units. The rights choice of materials ensures that reactions between material, product and cleaning devices have no negative impact on the product. Appropriate surface designs support clean ability and, thus, represent decisive factors in reducing cleaning times, cleaning cycles and cleaning costs.

US Food and Drug Administration (FDA)[1]

The Food and Drug Administration (FDA) is an agency within the U.S. Department of Health and Human Services.

FDA is responsible for

- Protecting the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products, medical devices, our nation's food supply, cosmetics, dietary supplements, and products that give off radiation.
- Regulating tobacco products
- Advancing the public health by helping to speed product innovations
- Helping the public get the accurate, science-based information they need to use medicines and foods to improve their health

European Hygienic Engineering & Design Group (EHEDG)[2]

EHEDG provides practical guidance on the hygienic engineering aspects of manufacturing safe and wholesome food. Founded in 1989, it is a consortium of equipment manufacturers, food companies, research and educational institutes as well as public health authorities whose common aim is to promote hygiene during the processing and packaging of food products. EHEDG actively supports European legislation, which requires that handling, preparation processing and packaging of food is done hygienically using hygienic machinery and in hygienic premises (EC Directive 98/37/EC, EN 1672-2 and EN ISO 14159).

This **EHEDG** guideline describe the principal design criteria to be met by hygienic and aseptic equipment for the manufacture of food, and gives guidelines on how to design and construct food machinery and equipment such that it does not adversely affect the microbiological safety and quality of the product. Suitable product contact materials are described, as well as aspects of fabrication such as surface finish, supports, welding and insulation. The guidelines apply to durable equipment used for batch and continuous, open and closed manufacturing operations.

1 http:// www.fda.org
2 http:// www.ehedg.org

Equipment certification

Authorized EHEDG institutes are offering certification to the benefit of both equipment suppliers and food manufacturers:

Equipment suppliers:

- Their equipment can be approved by EHEDG authorized organizations to be in compliance with EHEDG criteria. In certain cases, approval may only be granted after testing by a laboratory accredited by a notified body, using EHEDG test methods.

Food manufacturers:

- They may select hygienically designed equipment although acquires must still validate that such equipment is adequate for its intended use.

3-A Sanitary Standards[1]

3-A SSI formulates sanitary standards and accepted practices for the sanitary design, fabrication, installation and clean ability of dairy and food equipment or systems used to handle, process and package consumable products where a high degree of sanitation is required. These sanitary standards and accepted practices are developed through the cooperative efforts of industry experts. 3-A Sanitary Standards provide material specifications, design criteria and other necessary information for equipment types to satisfy public health concerns. 3-A Sanitary Standards are available for many equipment types, from fittings to silo tanks. The goal of 3-A SSI is to protect consumable products from contamination and to ensure that all product surfaces can be mechanically (CIP) cleaned or easily dismantled for manual cleaning.

3-A criteria is universally accepted by equipment manufacturers, fabricators, users and sanitarians.

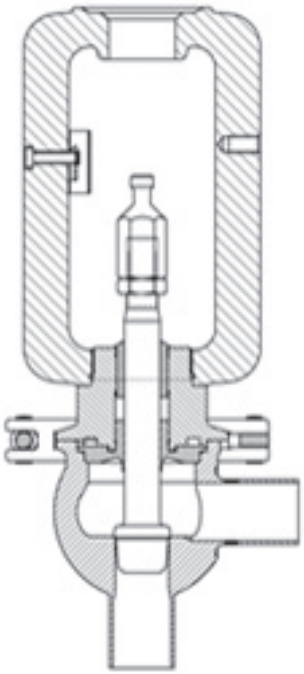
Figure 6.5.1.-1: Type 3347

Type 3347 Angle Valve with:

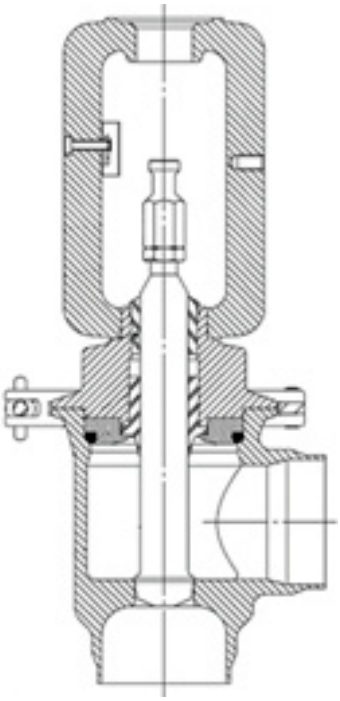
- Type 3271 Pneumatic Actuator (Type 3347-1 Control Valve) or
- Type 3277 Pneumatic Actuator (Type 3347-7 Control Valve) for integral positioner attachment
- Cavity-free valve body made of stainless steel
- FDA conformity for wetted sealing materials
- 3-A conformity for Type 3277 Pneumatic Actuator and approved valve accessories
- Valve plug with metal or soft sealing
- Easily detachable clamp connection between body and bonnet
- Suitable for cleaning-in-place (CIP)

1 http://www.3-a.org

Construction



Ball body



Caste body

Applications Type 3249

Figure 6.5.1.-2: Aseptic Valve Type 3249-7 for pharmaceutical plants

Surface of special Control valve for hygienic applications in the pharmaceutical and food processing industries

- With consideration of the volume
  - Bacteria 0.2 to 3.0 µm
  - Yeast 2.0 to 15 µm
- Mechanical and electro polishing. Electro polishing doesn't systematically improve Ra value

Note: 1 Ra value ≤ 1.0 µm (0.8 µm) is necessary for the product-contact surfaces

Different finishes:

- Standard finish Ra 1,0 or 0,8
- Polished Ra 0,6
- Polished Ra 0,4

Figure 6.5.1.-3: Ball body

Types of connection	
Unchangeable connection	**Changeable connection**
■ Welding ends for pipes acc. to ▪ DIN 11850 ▪ ISO 2037 ▪ BS 4825 ▪ DIN EN ISO 1127 ▪ SMS	■ Clamp connection acc. to ▪ ISO 2852, DIN 32676 or BS 4825 ■ Flange connection acc. to ▪ DIN 2501, ANSI B16.1 or DIN EN 11864 ■ Threaded couplings acc. to ▪ DIN 11887, DIN EN 11864, SMS

Table 6.5.1.-4: Types of connections

Hundreds of connections for the pharmaceutical and food processing industries.

Figure 6.5.1.-5: Connections for the pharmaceutical and food processing industries